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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/743,557	Applicant(s) SADOZAI ET AL.	
	Examiner COURTNEY BROWN	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/22/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 22, 2010 has been entered.

Acknowledgement of Receipt/Status of Claims

This Office Action is in response to the amendment filed July 22, 2010. Claims 11-22 are pending in the application. Claims 1-10 have been cancelled. Claim 1 has been amended. Claims 11-22 are being examined for patentability.

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

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Information Disclosure Statement

The Information Disclosure Statements (IDS) submitted on July 22, 2010 has been considered by the examiner.

New Rejection(s) Necessitated by the Amendment filed on June 22, 2010

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leshchiner et al. (US Patent 5,143,724) in combination with Fujita et al. (JP 2000230001 A) in view of Chasin et al. (US Patent 5,942,241), Aeschlimann et al. (US Patent 7196180) and Calias et al. (US Patent 6521223 B1).

Applicant's Invention

Applicant claims a method of augmenting tissue in a subject that is in need of tissue augmentation, the method comprising: a) inserting a needle into a subject at a location in the subject that is in need of tissue augmentation, wherein the needle is coupled to a syringe loaded with a cross linked HA (i.e., hyaluronic) composition that includes cross linked, water-insoluble, hydrated HA gel particles, wherein the HA includes crosslinks represented by the following structural formula: HA'--U--R2--U--HA' wherein: each HA' is the same or different cross linked HA' molecule; each U is independently an optionally substituted O-acyl isourea or N-acyl urea; and R2 is

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optionally substituted alkyl, alkenyl, alkynyl, alkoxy, cycloalkyl, cycloalkenyl, cycloalkynyl aryl, heteroaryl, heterocyclyl, cycloaliphaticalkyl, aralkyl, heteroaralkyl, or heterocyclylalkyl, wherein the HA gel particles have an average particle diameter distribution selected from the group consisting of a hydrated particle average diameter between about 20 gm and about 1000 gm, and a dehydrated particle average diameter between about 10 gm and about 500 gm; and wherein the cross linked HA composition is a single hydrated particle phase; and b) applying force to the syringe, whereby at least a portion of the cross linked HA composition is delivered into the subject; wherein the cross linked HA composition is stable in the subject for at least 8 weeks.

***Determination of the scope and the content of the prior art
(MPEP 2141.01)***

Leshchiner et al. teach the application of biocompatible viscoelastic gel slurries comprising swollen polymeric gel particles uniformly distributed in a second phase (column 2, lines 59-65) for soft tissue augmentation wherein the basic properties of the mixed gel slurries including: biocompatibility; controlled viscoelasticity and diffusion characteristics; easily controlled residence time at the site of implantation; and easy handling of the material allows its injection through a small diameter needle (column 9, lines 10-22). Leschiner et al. teach the use of a variety of polymeric gels such as hyaluronan (i.e., hyaluronic acid and its biologically acceptable salts) for use in the aforementioned slurries (column 2, line 66 bridging to column 3, lines 1-5) wherein said polymeric gels can be made of polymers which have been insolubilized by cross

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linking (column 3, lines 23-35). Leshchiner et al. teach that said viscoelastic gel mixtures may contain many other components such as various physiologically active substances, including drugs (column 7, lines 60-end). In Examples 1-4, Leshchiner et al. teach that the rheological properties of the aforementioned viscoelastic gel mixtures were evaluated with the Bohlin Rheometer System which is a computerized rheometer with controlled shear rate and which can operate in three modes: viscometry, oscillation and relaxation wherein measurements of viscoelastic properties at various frequencies characterize the balance between elastic (storage modulus G') and viscous (loss modulus G'') properties (column 9, lines 32-end). In light of the fact that Leshchiner et al. teach the use of the Bohlin Rheometer System to measure the storage modulus G' and the other viscoelastic properties, it is the Examiner's position that the storage modulus G' and the kinematic viscosity of the instant composition can only be determined experimentally (claims 20-22 of the instant application).

Fujita et al. teach a medical material with an especially high biocompatibility which is produced by incorporating a gel formed from hyaluronic acid. Fujita et al. teach that said gel is crushed with a suitable crusher to an average particle size of 10 μm or smaller (preferably 10-5000 micrometers, see [0019]) and used for injection and then suspended in a concentration of 0.1-5 wt.% in an arbitrary solution, giving a gel slurry suitable for in-vivo decomposable medical materials and cosmetics (abstract). In reference to claim 18, wherein the instant invention requires that the a multimodal distribution, the specification discloses, on page 13, lines 3-7, that "**the resulting**

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composition has an average diameter distribution that is different from the ground particles before sizing, for example, the average diameter distribution can be a multimodal average diameter distribution, e.g., a bimodal average diameter distribution when two average diameter fractions are selected for the composition. The properties of the multimodal composition are built from the properties of the individual average diameter fractions and their amounts in the composition.” Therefore, it is the Examiner's position that if the instant composition has multiple average diameter fractions, it is taught by Fujita et al. Further, the U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

***Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)***

The difference between the invention of the instant application and that of Fujita et al. and Leshchiner et al. is that Fujita et al. and Leshchiner et al. do not expressly teach the use of lidocaine HCL as an anesthetic. This deficiency in Fujita et al. and Leshchiner et al. is cured by the teachings of Chasin et al. Chasin et al. teach the use of a local anesthetic such as lidocaine (see claim 8 of reference) that can be formulated

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in injectable microspheres in combination with at least one augmenting agent (column 10, lines 20-24). Chasin et al. also teach the use of hyaluronic acid as a preferred controlled release material (column 12, lines 43-56).

The difference between the invention of the instant application and that of Fujita et al. and Leshchiner et al. is that Fujita et al. and Leshchiner et al. do not expressly teach a hyaluronic acid (HA) composition that is cross-linked with different compounds such as an optionally substituted o-acyl isourea or N-acyl urea. This deficiency in Fujita et al. and Leshchiner et al. is cured by the teachings of Aeschlimann et al. Aeschlimann et al. teach introducing a functionalized side chain onto HA wherein the direct carbodiimide-mediated coupling of amines to the carboxyl group of HA in an aqueous environment, with EDC (1-ethyl-3-[3-dimethylaminopropyl] carbodimide), produces O-acyl isourea which is formed as a reactive intermediate that rearranges rapidly to a stable N-acyl urea (see column 12, line 48 bridging to column 13, lines 1-5).

The difference between the invention of the instant application and that of Fujita et al. and Leshchiner et al. is that Fujita et al. and Leshchiner et al. do not expressly teach a cross linked hyaluronic acid (HA) composition that is a single hydrated phase. This deficiency in Fujita et al. and Leshchiner et al. is cured by the teachings of Calias et al. Calias et al. teach single phase gels for preventing the formation of surgical adhesions. Said gels are prepared by reacting an aqueous solution of a polyanionic polysaccharide, such as hyaluronic acid or carboxymethyl cellulose, with divinyl sulfone, to form a gel, the solution is neutralized, and **a solid is precipitated from the solution**

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(i.e., hydrated particle of instant application). The solid can be redissolved in water to form a gel having properties which can be modified to suit a particular application (abstract).

The difference between the invention of the instant application and that of Fujita et al. and Leshchiner et al. is that Fujita et al. and Leshchiner et al. do not expressly teach that the cross linked HA composition is stable in the subject for at least 8 weeks.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Fujita et al., Leshchiner et al. and Chasin et al. to arrive at a method of augmenting tissue in a human comprising the use of a cross-linked hyaluronic acid (HA) composition that is cross-linked with different compounds such as an optionally substituted o-acyl isourea or N-acyl urea. One skilled in the art at the time the invention was made would have been motivated to use hyaluronic acid (HA) composition that is cross-linked with different compounds such as an optionally substituted o-acyl isourea or N-acyl urea because each of the aforementioned references teach hyaluronic acid compositions useful in a method of augmenting tissue. Thus, in view of *In re Kerkhoven*, 205 USPQ 1069 (C.C.P.A. 1980), it is *prima facie* obvious to combine two or more compositions each of which is taught by prior art to be

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useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in prior art, thus claims that requires no more than mixing together two or three conventional hyaluronic acid compositions used for tissue augmentation set forth *prima facie* obvious subject matter.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Fujita et al., Leshchiner et al. and Aeschlimann et al. to arrive at a method of augmenting tissue in a human comprising the use of a cross-linked hyaluronic acid (HA) composition and lidocaine HCL as an anesthetic. One skilled in the art at the time the invention was made would have been motivated to use lidocaine HCL as an anesthetic because each of the aforementioned references teach hyaluronic acid compositions useful in a method of augmenting tissue. Thus, in view of *In re Kerkhoven*, 205 USPQ 1069 (C.C.P.A. 1980), it is *prima facie* obvious to combine two or more compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in prior art, thus claims that requires no more than mixing together two or three conventional hyaluronic acid compositions used for tissue augmentation set forth *prima facie* obvious subject matter.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Fujita et al., Leshchiner et al. and Calias et al. to use a cross linked hyaluronic acid (HA) composition that is a single hydrated phase in a

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method of augmenting tissue. One skilled in the art would have been motivated to use a cross linked hyaluronic acid (HA) composition that is a single hydrated phase Calias et al. teach that two phase gel slurries do suffer from certain drawbacks. For instance, Calias et al. teach that the material must be processed correctly in order to improve the handling properties of the material, and to permit its therapeutic application through the narrow openings of needles and other applicators, particularly for minimally invasive surgical indications. Such processing requires the use of processing equipment and the application of shear forces to the material, which in turn can result in a decrease in viscosity (thinning). Calias et al. teach that two phase materials contain dispersed, heterogeneous particles which tend to plug the narrow openings of such delivery systems and that a single phase, homogeneous composition is more useful in minimally invasive surgical applications where devices are introduced into the body through narrow access ports. Therefore, Calias et al. teach that it would be highly desirable to formulate a single phase gel solution which is capable of preventing the formation of adhesions, and which can be easily handled and stored for future use, and which possesses the advantageous characteristics of two phase gels (column 2, line 61 bridging to column 3, lines 1-12). Therefore, given the state of the art as evidenced by the teachings of the cited references, and absent any evidence to the contrary, there would have been a reasonable expectation of success in combining the teachings of the cited references to use a HA composition that is single hydrated particle phase in a method of augmenting tissue.

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With regard to amended claim 11, Fujita et al. and Leshchiner et al. do not expressly teach that the cross linked HA composition is stable in the subject for at least 8 weeks. However, the U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Examiner's Response to Applicant's Remarks

Applicant's arguments filed on July 22, 2010, with respect to the 103 rejection of claims 11-16 and 18-22 under 35 U.S.C. 103(a) as being unpatentable over Leshchiner et al. (US Patent 5,143,724) in combination with Fujita et al. (JP 2000230001 A) in view

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of Chasin et al. (US Patent 5,942,241), Aeschlimann et al. (US Patent 7196180) and Calias et al. (US Patent 6521223 B1) have been fully considered but they are moot in view of the new grounds of rejection. However, the Examiner has addressed the arguments that do not pertain to newly amended claim 11 since the teachings of Leshchiner et al., Fujita et al., Chasin et al. and Aeschlimann et al. are used in the instant rejection.

Applicant states that that the phrase "a single hydrated particle phase", as defined in the instant specification, means that "any liquid in the composition is essentially contained in the hydrated particles, e.g., there is essentially no free liquid phase" (§ 50). Applicant argues that Leshchiner discloses two-phase gel slurries (Leshchiner at col. 2, lines 61-65). Fujita teaches a gel slurry (Fujita at abstract and §§ 7-8), and that the Office Action of January 25, 2010 admits that this is not a single hydrated particle phase. However, the Examiner disagrees with Applicant's argument because the teaching of Calias et al. was used to show that the use of a single hydrated particle phase was known at the time the instant application was filed. Calias et al. teach single phase gels for preventing the formation of surgical adhesions. Said gels are prepared by reacting an aqueous solution of a polyanionic polysaccharide, such as hyaluronic acid or carboxymethyl cellulose, with divinyl sulfone, to form a gel, the solution is neutralized, and a solid is precipitated from the solution (i.e., hydrated particle of instant application).

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Applicant states that Chasin teaches "pharmaceutically acceptable augmenting agent or agents in conjunction with a local anesthetic in controlled release form that significantly increases the time period of local anesthesia when administered at a site in a patient" (Chasin at col. 5, lines 31-27) and that Aeschlimann discloses a "method for chemical crosslinking of high molecular weight hyaluronic acid under physiological conditions" (Aeschlimann at col. 5, lines 12-14). Applicant argues that none of these references teach or suggest a single hydrated particle phase of cross linked HA particles for use in a method of tissue augmentation. Applicant further argues that Calias' material is unsuitable for tissue augmentation and that Calias discloses that their gel is suitable for use in preventing surgical adhesions. Applicant argues that Calias is completely silent with regard to tissue augmentation. Thus, Applicant concludes that Calias provides no teaching, suggestion, or motivation to use Calias' material in a method of tissue augmentation. However, the Examiner disagrees with Applicant's argument because Calias et al. teach that two phase gel slurries do suffer from certain drawbacks. For instance, Calias et al. teach that the material must be processed correctly in order to improve the handling properties of the material, and to permit its therapeutic application through the narrow openings of needles and other applicators, particularly for minimally invasive surgical indications. Such processing requires the use of processing equipment and the application of shear forces to the material, which in turn can result in a decrease in viscosity (thinning). Calias et al. teach that two phase materials contain dispersed, heterogeneous particles which tend to plug

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the narrow openings of such delivery systems and that a single phase, homogeneous composition is more useful in minimally invasive surgical applications where devices are introduced into the body through narrow access ports. Therefore, Calias et al. teach that it would be highly desirable to formulate a single phase gel solution which is capable of preventing the formation of adhesions, and which can be easily handled and stored for future use, and which possesses the advantageous characteristics of two phase gels (column 2, line 61 bridging to column 3, lines 1-12). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Calias et al. teach. that hyaluronic acid, in chemically modified form, is known to be useful as a surgical aid to prevent adhesions and accretions of body tissues during the post-operation period. The chemically modified hyaluronic acid gel or film is injected or inserted into the locus between the tissues that are to be kept separate to inhibit their mutual adhesion (column 1, lines 57-62). The instant claims are drawn to a method of augmenting tissue in a subject comprising inserting a needle into a subject wherein the needle is coupled to a syringe loaded with a cross linked

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hyaluronic acid. Thus, Calias et al. do provide teaching, suggestion, or motivation to use their material in a method of tissue augmentation.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Conclusion

The claims remain rejected.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney A. Brown whose telephone number is 571-270-3284. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Ernst V Arnold/
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